IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

MARY HOVEY,

Plaintiff,

v. CIVIL ACTION NO. 2:13-cv-18900

COOK INCORPORATED, et al.,

Defendants.

MEMORANDUM OPINION AND ORDER

Pending before this court is the defendants' Motion for Summary Judgment ("Motion") [Docket 34]. For reasons explained below, the Motion is **DENIED**.

I. Background

This case against Cook Inc., Cook Biotech, Inc., and Cook Medical, Inc. (collectively "Cook") resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI").[1] In the seven MDLs, there are more than 70,000 cases currently pending, approximately 350 of which are in the Cook MDL, MDL 2440. The instant case was selected as a bellwether case to be tried before a jury on June 8, 2015. (*See* Pretrial Order # 52, *In re: Cook Med. Inc. Pelvic Repair Sys. Prods. Liab. Litig.*, No. 2:12-cv-2440, entered Jan. 13, 2015, *available at* http://www.wvsd.uscourts.gov/MDL /2440/orders.html).

[1] In the interest of clarity, I note that the pelvic repair products manufactured by Cook do not contain polypropylene mesh like most of the products at issue in the other MDLs before this court. Rather, Cook manufactures its products using a biologic material made from porcine small intestinal submucosa ("SIS"), (Compl. [Docket 1] ¶ 5), which, in layman's terms, is the tissue from the small intestine of a pig.

On May 15, 2003, the plaintiff, Mary Hovey, was implanted with the Stratasis Urethral Sling ("Stratasis") manufactured by Cook to treat SUI. (Compl. [Docket 1] ¶ 27). Dr. Robert May Jr. performed Ms. Hovey's surgery at Christus Spohn Hospital Shoreline in Corpus Christi, Texas. (*Id.*; Pl.'s Br. in Opp. to Cook's Mot. for Summ. J. ("Pl.'s Br. in Opp.") [Docket 47], at 1). About seven days after her surgery, Ms. Hovey returned to Dr. May for a follow-up examination, and he determined that her surgery went well. (May Dep. [Docket 47-2], at 64:22–65:4). Then, on May 28, 2003, Ms. Hovey visited the emergency room with complaints of fever and pain at the site of the surgical incision. (Hovey Dep. [Docket 47-1], at 29:18–22). Dr. May discovered an abscess near the incision that, in his opinion, was likely the cause of her pain. (May Dep. [Docket 47-2], at 68:17–19). Dr. May discussed with Ms. Hovey several options for handling the pain, including drainage of the abscess and removing the infection surrounding the sling, if any. (*Id.* at 72:22–73:2). Ms. Hovey opted for the former, less invasive procedure. (*Id.* at 73:25–74:2). Therefore, Dr. May drained the abscess, and Ms. Hovey was discharged on June 4, 2003. (*Id.* at 74:25–75:1). Since this procedure, Ms. Hovey has experienced renewed incontinence, (*id.* at 36:7–19), urinary tract infections, (*id.* at 44:10–22), pain with intercourse, (*id.* at 19:3–7), and pain around the abscess wound, (*id.* at 46:22–25). None of the doctors that Ms. Hovey saw about these problems indicated to her that the Stratasis could be the cause. (*Id.* at 47:20–24). According to Ms. Hovey, she did not become aware that the Stratasis could be responsible for her problems until February 4, 2013, when she s transvaginal mesh on the Internet. (Hovey Aff. [Docket 47-3], at 1). She then contacted an attorney and filed suit on July 10, 2013. (*Id.*).

Ms. Hovey claims that as a result of the implantation of the Stratasis, she has suffered "extreme pain, tenderness, fever, inflammatory reaction, severe infection, abscess formation, pain with voiding, fibrosis, wound dehiscence, scarring, recurrence, bleeding, and dyspareunia." (Pl.

Fact Sheet [Docket 51-1], at 9–10). She brings the following claims against Cook: failure to warn under the Product Liability Act, strict liability, negligence, negligent misrepresentation, negligent infliction of emotional distress, breach of express warranty, breach of implied warranty, violation of consumer protection laws, gross negligence, unjust enrichment, and punitive damages. (Compl. [Docket 1] ¶¶ 44–133). In the instant motion, Cook argues that each of the plaintiff's claims is barred by Texas's statute of limitations and preempted by the Food, Drug, and Cosmetic Act ("FDCA"). (*See* Cook's Br. in Supp. of Mot. for Summ. J. ("Cook's Br. in Supp.") [Docket 35], at 1). Consequently, Cook asks this court to grant summary judgment in favor of Cook and dismiss Ms. Hovey's case in its entirety.

II. Legal Standards

A. Summary Judgment

To obtain summary judgment, the moving party must show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). In considering a motion for summary judgment, the court will not "weigh the evidence and determine the truth of the matter." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986). Instead, the court will draw any permissible inference from the underlying facts in the light most favorable to the nonmoving party. *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 587–88 (1986).

Although the court will view all underlying facts and inferences in the light most favorable to the nonmoving party, the nonmoving party nonetheless must offer some "concrete evidence from which a reasonable juror could return a verdict in his [or her] favor." *Anderson*, 477 U.S. at 256. Summary judgment is appropriate when the nonmoving party has the burden of proof on an essential element of his or her case and does not make, after adequate time for discovery, a

showing sufficient to establish that element. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322–23 (1986). The nonmoving party must satisfy this burden of proof by offering more than a mere "scintilla of evidence" in support of his or her position. *Anderson*, 477 U.S. at 252. Likewise, conclusory allegations or unsupported speculation, without more, are insufficient to preclude the granting of a summary judgment motion. *See Felty v. Graves-Humphreys Co.*, 818 F.2d 1126, 1128 (4th Cir. 1987); *Ross v. Comm'ns Satellite Corp.*, 759 F.2d 355, 365 (4th Cir. 1985), *abrogated on other grounds*, 490 U.S. 228 (1989).

B. Choice of Law

Under 28 U.S.C. § 1407, this court has authority to rule on pretrial motions in MDL cases. The choice of law for these pretrial motions depends on whether they concern federal or state law:

> When analyzing questions of federal law, the transferee court should apply the law of the circuit in which it is located. When considering questions of state law, however, the transferee court must apply the state law that would have applied to the individual cases had they not been transferred for consolidation.

In re Temporomandibular Joint (TMJ) Implants Prods. Liab. Litig., 97 F.3d 1050, 1055 (8th Cir. 1996) (internal citations omitted). To determine the applicable state law for a dispositive motion based on the statute of limitations, I generally refer to the choice-of-law rules of the jurisdiction where the plaintiff first filed her claim. *See In re Air Disaster at Ramstein Air Base, Ger.*, 81 F.3d 570, 576 (5th Cir. 1996) ("Where a transferee court presides over several diversity actions consolidated under the multidistrict rules, the choice of law rules of each jurisdiction in which the transferred actions were originally filed must be applied."); *In re Air Crash Disaster Near Chi., Ill.*, 644 F.2d 594, 610 (7th Cir. 1981); *In re Digitek Prods. Liab. Litig.*, MDL No. 2:08-md-01968, 2010 WL 2102330, at *7 (S.D. W. Va. May 25, 2010). However, if a plaintiff files her claim directly into the MDL in the Southern District of West Virginia, as Ms. Hovey did in this case, I

consult the choice-of-law rules of the state in which the plaintiff was implanted with the product. *See Sanchez v. Boston Scientific Corp.*, 2:12-cv-05762, 2014 WL 202787, at *4 (S.D. W. Va. Jan. 17, 2014) ("For cases that originate elsewhere and are directly filed into the MDL, I will follow the better-reasoned authority that applies the choice-of-law rules of the originating jurisdiction, which in our case is the state in which the plaintiff was implanted with the product."). Ms. Hovey received the Stratasis implantation surgery in Texas. Thus, the choice-of-law principles of Texas guide this court's choice-of-law analysis.

The parties agree, as does this court, that these principles compel application of Texas law to the plaintiff's claims. In tort actions, Texas adheres to the Restatement (Second) of Conflict of Laws. *Gutierrez v. Collins*, 583 S.W.2d 312, 318 (Tex. 1979). Under Section 145 of the Second Restatement, the court must apply the law of the state with the most "significant relationship to the occurrence and the parties." Restatement (Second) of Conflicts of Laws § 145 (1971). Here, Ms. Hovey resides in Texas, and the product was implanted in Texas. Thus, I apply Texas's substantive law to this case, beginning with Cook's statute-of-limitations argument and then turning to Cook's preemption argument.

III. Statute of Limitations

The plaintiff's personal injury claims—strict liability, negligence, and breach of warranties—are governed by a two-year statute of limitations. Tex. Civ. Prac. & Rem. Code Ann. § 16.003(a) (2013). The plaintiff's claim for violation of the consumer protection laws, apparently asserted under Texas's Deceptive Trade Practices-Consumer Protection Act ("DTPA"), is also subject to a two-year statute of limitations. Tex. Bus. & Com. Code Ann. § 17.565 (2013).[2]

[2] In her Brief in Opposition, the plaintiff clarifies that she does not pursue any UCC-based warranty claims. (Pl.'s Br. in Opp. [Docket 47], at 1 n.1). Accordingly, the court does not address Cook's arguments relating to the UCC, as they are moot.

Although the limitations period is the same, different rules apply to determining the time of accrual for these claims, and therefore, I divide my analysis into two sections: (A) the plaintiff's personal injury claims and (B) the plaintiff's DTPA claims.

A. Personal Injury Claims

As stated above, in Texas, a personal injury action must be filed "not later than two years after the day the cause of action accrues." Tex. Civ. Prac. & Rem. Code Ann. § 16.003(a). Generally, a cause of action accrues "when a wrongful act causes some legal injury, even if the fact of injury is not discovered until later, and even if the resulting damages have not yet occurred." *S.V. v. R.V.*, 933 S.W.2d 1, 4 (Tex. 1996). In some circumstances, however, Texas courts have given exception to this definition of accrual through application of the discovery rule, which provides that an action does not accrue "until the plaintiff knew or in the exercise of reasonable diligence should have known of the wrongful act and resulting injury." *Id.* A plaintiff can call upon the discovery rule when "the nature of the injury incurred is inherently discoverable and the evidence of injury is objectively verifiable." *Id.* at 6.

The plaintiff argues that although she sustained her injuries soon after she received the Stratasis implant in 2003, the discovery rule operates to toll the limitations period until February 2013, when she saw an "internet pop-up regarding transvaginal mesh litigation, which caused her to seek representation." (Pl.'s Br. in Opp. [Docket 47], at 9). Accordingly, in the plaintiff's view, her claim, filed on July 11, 2013, is timely. Cook, on the other hand, contends that Texas law does not permit the plaintiff to invoke the discovery rule because her injuries were not "inherently undiscoverable." (Cook's Br. in Supp. [Docket 35], at 9). Furthermore, even if the discovery rule did apply, Cook argues that it was triggered on May 28, 2003, when Ms. Hovey returned to the

hospital with an abscess that resulted from her implantation surgery, and as a result, her lawsuit, filed ten years later, is time-barred. (*Id.* at 11).

I first consider whether the discovery rule applies to Ms. Hovey's claims. The Texas Supreme Court has explained its "general principle" on this matter as follows:

> [A]ccrual of a cause of action is deferred [by the discovery rule in] cases in which the alleged wrongful act and resulting injury were inherently undiscoverable at the time they occurred but may be objectively verified.

S.V., 933 S.W.2d at 6. Targeting the first element of this principle, Cook argues that Ms. Hovey's injuries, which she was aware of and received treatment for in May 2003, were not inherently undiscoverable, and so the discovery rule is inapplicable here. This position incorrectly interprets the above rule, which allows for application of the discovery rule when the "alleged wrongful act *and* the resulting injuries" are both inherently undiscoverable, that is, "unlikely to be discovered within the prescribed limitations period despite due diligence." *Id.* at 6–7 (emphasis added). Together, the "alleged wrongful act and the resulting injuries" are considered the "nature of the injury." *Id.* at 6. Here, although Ms. Hovey experienced the injuries she now complains of on May 28, 2003, she did not know, and was unlikely to discover before expiration of the statutory period, that a wrongful act (a defect in the Stratasis) was to blame. In other words, the "nature" of her injuries was inherently undiscoverable. Thus, I conclude that the discovery rule is available to the plaintiff in this case.

This conclusion primarily arises from the findings of federal courts applying Texas law to comparable facts. These courts have consistently ruled that the nature of injuries arising from implanted medical devices is inherently undiscoverable such that the discovery rule should be applied. *See Brandau v. Howmedica Osteonics Corp.*, 439 F. App'x 317, 322 (5th Cir. 2011) ("[T]he Fifth Circuit applying Texas law has repeatedly held that the discovery rule defers the

accrual of injuries resulting from implanted devices."). In *Pavich v. Zimmer, Inc.*, for example, the District Court for the Southern District of Texas held that the nature of injuries arising from defective orthopedic rods was inherently undiscoverable because "[t]here was no sudden trauma that caused the onset of his increased pain." 157 F.3d 903, at *2 (S.D. Tex. 1998). Rather, "[t]he broken rods were not visible to the naked eye, nor were the breaks readily discernable through palpation." *Id.* Therefore, the court found that the discovery rule was "properly applied" to the case. *Id.*; *see also Brandau*, 439 F. App'x at 321–22 (finding that the injury caused by the plaintiff's defective knee replacement is "in a category of injuries that have been identified as inherently undiscoverable under Texas law"); *Porterfield v. Ethicon, Inc.*, 183 F.3d 464, 467 (5th Cir. 1999) (applying Texas's discovery rule to a products liability claim brought by a plaintiff who had suffered problems resulting from surgically implanted mesh); *Woodruff v. A.H. Robins Co., Inc.*, 742 F.2d 228, 230 (5th Cir. 1984) (applying the discovery rule because although the plaintiff had "severe pelvic disease" years before filing suit, her cause of action against the Dalkon Shield manufacturer was inherently undiscoverable).

Ms. Hovey, like the plaintiff in *Pavich*, could not see the implant with her naked eye to observe any defects. Indeed, even Dr. May could not identify the sling when he operated to drain the abscess that Ms. Hovey developed after her surgery. (May Dep. [Docket 47-2], at 812:14–20). Therefore, the wrongful act and resulting injuries in this case likewise fall into the category of "inherently undiscoverable" under Texas law, and so the plaintiff can resort to the discovery rule to toll the statute of limitations.[3]

[3] Although the Texas Supreme Court has yet to address the narrow issue of the discovery rule's applicability in the context of implanted medical devices, its decisions on analogous issues support the federal courts' position and indicate that even if the plaintiff is aware of an injury, the responsible wrongful act might nevertheless be inherently undiscoverable such that the discovery rule should be implemented. The Texas Supreme Court's application of the discovery rule to cases involving latent occupational diseases is particularly instructive. In *Childs v. Haussecker*, the

The next question, then, is when Ms. Hovey "knew or in the exercise of reasonable diligence should have known of the wrongful act and resulting injury," thus satisfying the discovery rule and triggering the two-year statute of limitations. *S.V.*, 933 S.W.2d at 4. Texas requires more than knowledge of a causal connection between a product and the injury to trigger the statute of limitations:

> [W]hen the discovery rule applies, accrual is tolled until a claimant discovers or in the exercise of reasonable diligence should have discovered the injury and *that it was likely caused by the wrongful acts of another*.

Childs v. Haussecker, 974 S.W.2d 31, 40 (Tex. 1998) (emphasis added). It is undisputed that Ms. Hovey did not have actual knowledge that her injuries resulted from the "wrongful acts of another" until she saw an Internet advertisement on transvaginal mesh litigation in February of 2013. (Hovey Aff. [Docket 47-3], at 1). However, when she "should have" known this information—that is, when she had "knowledge of facts which would cause a reasonable person to diligently make inquiry to determine his or her legal rights," *Bell v. Showa Denko K.K.*, 899 S.W.2d 749, 754 (Tex. Ct. App. 1995)—presents a closer question. Cook maintains that a reasonable person would have investigated further into the product on May 28, 2003, when Dr. May mentioned to her that removal of the sling could possibly fix the abscess. (Reply [Docket 51], at 9–10). And since this time, Ms. Hovey has visited only two gynecologists about her pain and incontinence. (*See* Hovey

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court stated that "a latent injury or disease is the epitome of the type of injury that is often inherently undiscoverable within the applicable limitations period" because "even when symptoms do arise that make the fact of the injury objectively verifiable, the injury and its etiology are difficult to diagnose and ascertain because of the lengthy latency period, the many potential causes of the specific symptoms, and some physicians' lack of education and experience." 974 S.W.2d 31, at 38–39 (Tex. 1998). Similarly, in cases involving an implanted medical device, it is difficult to diagnose the etiology of the plaintiff's complications given the many potential causes, such as physician error, wound infection, or the normal risks of surgery. (*See, e.g.*, May Dep. [Docket 47-2], at 86:19–25 (explaining that the development of an abscess is not normal or expected from implantation of a Stratasis); *id.* at 102:3–9 (stating that he did not know the cause of the abscess at the time of treatment)). Cases from the Texas appellate courts also support the use of the discovery rule in these circumstances. *See, e.g.*, *Strasser v. Sulzer Medica U.S.A., Inc.*, No. 01-01-00610-CV, 2002 WL 1722186, at *4 (Tex. Ct. App. 2002) (applying the discovery rule to injuries arising from a prosthesis); *Martinez v. Humble Sand & Gravel, Inc.*, 940 S.W.2d 139, 144 (Tex. Ct. App. 1996) (applying the discovery rule to cases in which the plaintiff seeks damages for "permanent, disabling injuries" and holding that the claim accrues when the party "should reasonably have become aware of the permanent nature of his disease").

Dep. [Docket 47-1] at 34:14–39:5 (describing visits with Drs. Caceres and Cardenas)). Seeking the opinions of only two physicians over a ten-year period does not, in Cook's view, constitute the due diligence that is necessary to toll the statutory period under the discovery rule.

The plaintiff's ten-year delay in filing suit does cause the court some concern. But I nevertheless find that whether a reasonable person would have conducted further investigation under these circumstances is a question best left to the jury. As an initial matter, while Dr. May proposed the option of removing the sling as a means to alleviate the abscess, he did not believe this step necessary. (*See* May Dep. [Docket 47-2], at 73:25–14 ("I don't think she needed removal of the entire sling.")). In fact, he told Ms. Hovey that a less invasive procedure was available that would allow her to retain the sling and avoid recurrence of incontinence. (May Dep. [Docket 47-2], at 72:22–73:7 (explaining the conversation he had with Ms. Hovey about the possible treatment options)). Having been informed by her surgeon that removal of the sling was not necessary, Ms. Hovey chose the less invasive option, and Dr. May was able to fix the abscess by draining the fluid with cultures. (*Id.* at 78:3–9). In the months following this procedure, Ms. Hovey's wound closed, and her incontinence improved. (*Id.* at 93:7–95:21). Removal of the Stratasis was not mentioned again by Dr. May or any other physician. (*See* Hovey Dep. [Docket 47-1], at 43:3–9 ("Q: . . . Has any doctor recommended removal of the Cook biodesign or surgisis product? . . . A: No.")). Arguably, therefore, Ms. Hovey had no facts at this time that would warrant a reasonable person to investigate into the existence of a defect in the Stratasis. Nor would she have had such facts in the following years—although it is true that Ms. Hovey only sought the opinions of two other physicians during this time period, neither of them gave her any reason to believe that the Stratasis could be responsible for her symptoms. (*See id.* at 34:14–39:5 (describing visits with Drs. Caceres and Cardenas)).

Because none of Ms. Hovey's doctors identified a defect in the Stratasis as the cause of her injuries, a jury could find that Ms. Hovey did not possess facts that would lead a reasonable person to further investigate into wrongdoing until 2013, when Ms. Hovey saw an Internet advertisement. *See, e.g.*, *Strasser v. Sulzer Medica U.S.A., Inc.*, No. 01-01-00610-CV, 2002 WL 1722186, at *4 (Tex. Ct. App. 2002) (finding that the discovery rule was not "negated" until July 1998, when the plaintiff's doctor told him that there might be "a problem" with his prosthesis); *Childs*, 974 S.W.2d at 45 ("When medical experts consistently reject a layperson's suspicions concerning the cause of symptoms, . . . a fact question ordinarily arises about what reasonably should be known by the plaintiff and what further action the plaintiff should have taken . . . ."). I therefore leave the question of whether Ms. Hovey should have discovered the nature of her injury in May 2003 or in February 2013 to the factfinders. *Bell*, 899 S.W.2d at 754 (explaining that "whether a plaintiff discovered, or should have discovered, an injury is a question of fact which should be submitted to the trier of fact"). Cook's Motion regarding Ms. Hovey's personal injury claims is **DENIED**.

B. DTPA Claims

The DTPA provides a statutory discovery rule:

> All actions brought under this subchapter must be commenced within two years after the date on which the false, misleading, or deceptive act or practice occurred or within two years after the consumer discovered or in the exercise of reasonable diligence should have discovered the occurrence of the false, misleading, or deceptive act or practice.

Tex. Bus. & Com. Code Ann. § 17.565. As explained above, a jury could find that a reasonable person in Ms. Hovey's position could not have discovered through reasonable diligence any wrongdoing until she saw the Internet advertisement in February 2013. Therefore, I cannot

conclude as a matter of law that the statute of limitations has expired for Ms. Hovey's DTPA claims, and Cook's Motion on this matter is **DENIED**.[4]

IV. Preemption

Finally, Cook argues that the plaintiff's claims must be dismissed because they are federally preempted by § 360(k) of the FDCA, which provides that state law may not impose any requirement "different from, or in addition to" the requirements of the FDCA or any requirement "relat[ing] to the safety or effectiveness of the device." 21 U.S.C. § 360k(a) (2012). Cook contends that because the FDA approved the Stratasis for marketing under the FDCA's 510(k) clearance process, any state tort law claims regarding this product cannot survive.[5] Relying on the Supreme Court's opinion in *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 478 (1996), I have repeatedly rejected this argument.

In *Lohr*, the Supreme Court determined that the FDCA's preemption provision does not apply to products liability claims regarding medical devices that underwent 510(k) clearance rather than the premarket approval process. *Lohr*, 518 U.S. at 501–02. The Court found that because the 510(k) requirements did not relate to the safety or efficacy of the device, they did not preempt state tort claims:

> The generality of [the 510(k)] requirements make this quite unlike a case in which the Federal Government has weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on manufacturers or producers. Rather, the federal requirements reflect important but entirely generic concerns about device regulation generally, not the sort of concerns regarding a specific device or field of device regulation that the statute or regulations were designed to protect from potentially contradictory state requirements.

[4] Because I have found that Ms. Hovey's claims are saved by the discovery rule, I do not address Cook's argument that Ms. Hovey has not satisfied the elements of the doctrine of fraudulent concealment.

[5] For a discussion on the 510(k) clearance process and how it differs from the more vigilant premarket approval process, see *Lewis v. Johnson & Johnson*, 991 F. Supp. 2d 748, 751–52 (S.D. W. Va. 2014).

Id. at 501. From this, the Court reasoned that the FDCA's preemption provision does not apply to claims arising from products that received clearance through the 510(k) process. *Id.*

The arguments raised by Cook do not persuade me to abandon the Supreme Court's clear position on this matter. Cook argues that the 510(k) process has changed since the *Lohr* decision, and now, the FDA makes a safety and effectiveness determination when reviewing a product under 510(k). Specifically, Cook contends that the Safe Medical Device Act of 1990 ("SMDA"), which was enacted after the pacemaker at issue in *Lohr* had been cleared, "materially changed medical device regulation and specifically increased the robustness of the 510(k) process." (Cook's Br. in Supp. [Docket 35], at 17 (quoting Ralph Hall & Michelle Mercer, *Is* Lohr *Still Good Law?*, Food & Drug L. Inst. (2012))). Assuming the correctness of Cook's position—that the SMDA bolstered the 510(k) review process—the FDA's most recent guidance submits that the "evidentiary standard" applied to 510(k) is still less stringent than that applied in the premarket approval process. *See* FDA, *The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]: Guidance for Industry and Food and Drug Administration Staff* ("Guidance Document") 7 (July 28, 2014), *available at* http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm284443.htm (last visited Mar. 19, 2015). For premarket approval, the medical device must independently demonstrate safety and effectiveness. *Id.* at 6. In contrast, for 510(k) review, the FDA considers safety and effectiveness comparatively, "generally rel[ying], in part, on FDA's prior determination that a reasonable assurance of safety and effectiveness exists for the predicate device." *Id.* at 7. The analysis is predominantly relative, and the FDA does not engage in an independent investigation of the medical device's safety and effectiveness. *See id.* ("FDA generally evaluates differences between

the new device and the predicate device to determine their effect on safety and effectiveness.").

In sum, the language of the Guidance Document indicates that the FDA's 510(k) review continues to primarily focus on equivalence as opposed to safety, and as a result, I am doubtful the Supreme Court would change its clear position on this matter based on the SMDA. In fact, any changes imposed by the SMDA, which had already been in place for six years at the time of the *Lohr* decision, were available to the Court in interpreting Congress's intent for 510(k). *See Lohr*, 518 U.S. at 480 n.4 (recognizing Congress's enactment of the SMDA, which was "designed to reduce the FDA's reliance on the § 510(k) process while continuing to ensure that particularly risk devices received full [premarket approval] review"). Yet, the Court concluded that "[t]here is no suggesting in either the statutory scheme or the legislative history that the § 510(k) exemption process was intended to do anything other than maintain the status quo with respect to the marketing of existing medical devices and their substantial equivalents." *Id.* at 494. Furthermore, in *Riegel v. Medtronic, Inc.*, decided almost twenty years after the enactment of the SMDA, the Court again distinguished 510(k) clearance from the premarket approval process, explaining that "[w]hile § 510(k) is focused on *equivalence*, not safety, [citation omitted], premarket approval is focused on safety, not equivalence." 552 U.S. 312, 323 (2008). In light of *Lohr* and *Riegel*, I reject Cook's preemption argument and find that the 510(k) clearance of the Stratasis does not preempt the plaintiff's state tort claims. Cook's Motion on this issue is **DENIED**.

V. Conclusion

As explained above, Cook's Motion for Summary Judgment [Docket 34] is **DENIED**. The court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: April 1, 2015

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE